Chapter 8

5 A Day Community-Based Research

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INTRODUCTION

The National Cancer Institute (NCI) is the largest research Institute at the National Institutes of Health (NIH). From the perspective of NCI, research was and remains an essential component of the 5 A Day for Better Health Program. Chapter 7 provided an overview of the evaluation of the entire Program, including process and outcome studies. Of the outcome studies, the nine randomized community-based research grants were expected to provide the strongest evidence for an effect of the Program on consumption. They did, in fact, provide a positive answer to the following question: Can community-based 5 A Day interventions increase consumption of vegetables and fruit in diverse populations?

The purpose of this chapter is to provide an introduction to these grants, which are discussed in more detail in Chapters 9 through 11. This chapter will provide an understanding of the research environment from which the randomized community trials emerged, some insights into the development of the request for applications (RFA) to do this type of research, an overview of the nine grants, a brief description of some of the theories used in the grants, and results of the collaborative efforts among grantees.

RESEARCH ENVIRONMENT AT NCI IN THE 1980s AND 1990s

In the past few decades, the majority of research at NCI has been basic laboratory or clinical trial research. Historically, behavioral science was considered less robust and therefore has not been as well funded or respected. Community-based research is even further from NCI's "gold standard" of clinical trials than are clinically based behavioral studies. Therefore, it was important at the beginning of the 5 A Day Program to determine what kinds of studies would provide acceptable data in such an environment.

At the time that the 5 A Day Program was proposed, a number of behavioral science issues relevant to cancer prevention and control were under discussion at NCI. The Institute undertook the Women's Health Trial feasibility study in 1984 to decrease fat in the diets of high-risk women in an effort to reduce the incidence of breast cancer (Insull et al., 1990; Gorbach et al., 1990). Intense discussions about this research study at NCI meetings for external advisers revealed many issues of concern to scientists about prevention trials. Some researchers were skeptical that people would change their diets or that lower fat diets would be palatable. A lack of widely accepted biomarkers

of compliance was another concern. Finally, it was not yet clear that behavior change instead of disease outcome would be an acceptable research end point, despite the fact that the duration of research funding was usually not long enough to track disease outcomes in a prevention trial.

In addition, final data were not yet available from the first generation of community-based programs, such as the Minnesota Heart Health Program, funded by NIH's National Heart, Lung, and Blood Institute. Nevertheless, it appeared that another round of similar studies, with a small number of nonrandomized intervention and control communities, was unlikely to be funded. NIH staff scientists and scientific advisers perceived randomized trials and sample sizes larger than two to four communities to be the most robust research designs. Taking all these issues into account, NCI staff members developed a research plan for the 5 A Day Program that included behavioral end points, such as increased vegetable and fruit consumption, and larger numbers of randomized units (e.g., 12, 28) than those used in the heart disease trial (e.g., 2, 3). Such experimental designs would be the most acceptable way to prove the association between the program and its intended outcomes. In addition, well-controlled, community-based studies would build the strongest case for the program's continuation beyond its first 5 years.

THE IMPORTANCE OF THIS RESEARCH

A description of the research desired was announced through an RFA. The intent of the RFA was twofold: 1) to encourage research in the development of effective community-level interventions for changing dietary patterns by using a simple, positive, and actionable message and 2) to develop the community-level component of the national 5 A Day Program by providing the complementary and necessary interactive and environmental elements of successful behavior-change interventions. Those intervention elements included skills development, local media placement, social support, and modifications of foods offered in local food systems.

The 5 A Day RFA was only the second at NCI to focus entirely on community-based research on *nutrition*-related behaviors. Nutrition was sometimes a component of a multirisk-factor trial, such as the Working Well Research Trial (Heimendinger et al., 1995), or a part of a more general RFA, such as a previous one focused on capacity building (see Chapter 1), but nutrition as a focal point had received little emphasis. The 5 A Day RFA was the first to focus community-based nutrition intervention research on a common behavioral objective (i.e., to increase vegetable and fruit consumption consistent with the 5 A Day guidelines). One purpose for this focus was to produce a critical mass of nutrition research with comparable studies. This was also, in part, a strategy for strengthening NCI's portfolio of nutrition research grants.

Channel-specific grants for nutrition were new, although NCI's research program on smoking had for years successfully produced RFAs focused on specific channels, such as schools or physicians. A channel is a route for reaching consumers. It is usually an organization or entity, such as a school or worksite. Part of the vision for 5 A Day was that experienced, creative investigators would design interventions for a variety of channels and underserved populations, which could then be used by the 5 A Day Program and its national network of State health agencies and industry members. This diffusion of effective interventions could directly benefit U.S. taxpayers, whose taxes support NIH research.

DEVELOPMENT OF THE REQUEST FOR APPLICATION

With this vision in mind, NCI staff members followed the Institute's procedures for developing an RFA. A working group of external experts in nutrition and behavioral science was convened to discuss gaps in research, potential research designs, behavioral theories, and NCI's expectations.

The guidance provided by the working group was then used by staff to develop an RFA, which was released on March 27, 1992. Applications were due by June 9, 1992, giving researchers 2.5 months to respond. The total budget was $4 million per year for 4 years, or a total of $16 million for all grantees.

NCI invited applicants to develop, implement, and evaluate interventions in specific community-

based channels and for targeted specific populations to increase their consumption of vegetables and fruit using the 5 A Day message. The RFA also emphasized that vegetables and fruit were to be promoted in a manner that retained their integrity as low-fat foods and as part of an overall healthy eating pattern, in which these foods are seen as both low in fat and high in fiber.

Although the mechanism of support was a grant, applicants were advised that they would be asked to participate in a network of grantees for the purposes of sharing design and evaluation strategies, comparing results where possible, and distilling lessons learned from all grants combined. In addition, investigators were expected to supply a final report to assist with the dissemination of successful community-based intervention research.

UNIQUE ASPECTS OF THE REQUEST FOR APPLICATION

The most important provisions of the RFA were a focus on the simple 5 A Day message as well as use of specific channels, randomized designs in channels such as schools or worksites, larger sample sizes than some of those previously used in community research, behavioral theories, and collaboration between universities and health departments.

The 5 A Day message is, "Eat 5 or more servings of fruits and vegetables every day for good health." Guidelines for promoting products, the use of the 5 A Day logo, and the recipe criteria were provided in the RFA, along with a list of industry partners. The focus on a simple nutrition message was an innovation that had many advantages. Because the message was quantified, people could assess their own progress toward meeting the goal and did not have to interact with the medical system for a status report. Since most people like vegetables (71 percent) and fruit (82 percent), taste was not a barrier to increased consumption (Krebs-Smith et al., 1995a). With a single food-group focus, interventions were much easier to implement and measure than those that focused on either nutrients or the total diet.

For the 5 A Day Program, a channel was defined as a specific means or route for reaching consumers with messages, food, or both for the purpose of instilling the desired dietary behavior. Researchers then chose a target population within a particular channel. For example, within schools, either all students or students in specific grades might be targeted.

Researchers were encouraged to choose both a single channel and adequate numbers of randomized units to be able to test for statistical significance. The RFA indicated that randomization was clearly preferred to ensure that research designs would be as scientifically robust as possible. A detailed example of appropriate sample-size calculations was included.

In addition, the RFA stated that an issue of concern for all grants was the potential for contamination of the research from both the media and State-level activities of the national program. Therefore, it was important for each grantee to interact with its State-level coalition to collaborate where possible and to minimize possible contamination (i.e., overlapping of activities) of research sites by State-level efforts. The NCI National 5 A Day Program Office also requested that the State coalitions cooperate with the NCI-funded projects in their areas to help maintain the integrity of the proposed research designs. In general, this collaboration worked well—in some instances, State coalitions modified their planned activities to avoid promotions in areas with research subjects.

Seventy-three applications were received, indicating a high degree of interest in the topic. Such a high response exceeded the norm for cancer prevention grants at the time. Grants were reviewed using the NIH peer-review process. Funds were available to award only nine grants at an average of $450,000 per year for 4 years. The nine grants were funded in May 1993 and were scheduled to end in May 1997. Results of the studies began to appear in peer-reviewed journals in 1998. The nine studies are discussed briefly below. More detailed information on each grant is presented in Chapters 9 through 11.

OVERVIEW OF NINE GRANTS

Table 1 presents the characteristics of the nine grants, including the project location, lead agencies receiving the award, channels, and length of the intervention. (The California project included

Table 1. Nine Community-Based 5 A Day Grants

Project Location	*Lead Agencies*	*Channel*	*Length of Intervention*
Schools			
Alabama	• University of Alabama at Birmingham	• 28 schools • Grades 4-5	• 2 years • 14 lessons, 3 times/week over 5 weeks + parents + school food service
Georgia	• Emory University	• 16 schools • Grades 4-5	• 2 years • 2 sessions/week for 6 weeks
Louisiana	• Tulane University School of Public Health	• 12 schools • Grades 9-12	• 3 years • Monthly promotions, five 55-minute workshops + parents + school food service
Minnesota	• Minnesota Department of Health • University of Minnesota	• 20 schools • Grades 4-5	• 2 years • 16 lessons, 2 times/week over 8 weeks + parents + school food service + industry
Worksites			
Arizona	• University of Arizona (Arizona Cancer Center)	• 82 informal social networks at 10 worksites	• 18 months general program, 9 months peer program
Massachusetts	• Harvard University (Dana-Farber Cancer Institute)	• 22 community health centers	• 2 years: kickoff; ten 30-minute skills-building sessions, 1 campaign/year (3-5 weeks) + environmental changes
Washington	• Fred Hutchinson Cancer Research Center • University of Washington	• 28 worksites with cafeterias	• 1 year • Kickoff, constant messages, self-help manual, contests + environmental changes
Churches North Carolina	• North Carolina Department of Health • University of North Carolina	• 50 churches in 10 randomized counties	• 2 years—monthly packets, two educational sessions, tailored bulletins + environmental changes
WIC Maryland	• University of Maryland	• 15 sites in 6 counties	• 6 months • Three 45-minute sessions, four tailored letters

in Chapter 10 is excluded from this summary because it was not funded through the RFA and did not have to respond to the same requirements.) The grants intervened in schools (four), worksites (three), churches (one), and the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) (one). Three of the school grants were for the fourth grade, and the studies followed the children into the fifth grade. One of the grants addressed high school students and followed a freshman class from the end of the 9th grade through 12th grade. All worksite projects addressed public-sector worksites, although the Washington State project also included private-sector employees. The Massachusetts project intervened in community health centers; Arizona's intervened in the trades and labor segments of public-sector employers, such as universities and State government; and Washington's intervened in larger public- and private-sector employers that had cafeterias. North Carolina's project intervened in African-American churches located in 10 counties around the State. The Maryland project intervened in the WIC program in six counties, reaching WIC recipients who were pregnant, postpartum, or breast-feeding, or who were mothers of WIC preschoolers.

The number of randomization units ranged from 10 counties (covering 50 churches) in North Carolina to 82 social networks (at 10 worksites) in

Arizona. Length of the interventions ranged from 6 months in the WIC sites in Maryland to 3 years in the high schools in Louisiana. The average intervention length was 2 years.

Eight grants were awarded to universities and one to State health departments. The goal of generating collaboration between health departments and universities was achieved; each grant except one had such a collaboration. All grants had appropriate collaborative partners, such as State affiliates of the American Cancer Society, school boards, the U.S. Department of Agriculture's (USDA) Cooperative Extension Service agencies, and/or 5 A Day industry members (Havas et al., 1994, 1995).

Outcome Measures

The primary outcome for all studies was increased vegetable and fruit consumption. Measures of this outcome included food frequencies (which query how often a person eats foods listed), 24-hour recalls (respondents list all foods eaten) of a sample of the population, observations of children in the lunchroom, a single-item question ("How many servings of vegetables and fruit do you eat each day?"), and a seven-item questionnaire on food frequency. Both the single-item question and the seven-item questionnaire were common instruments used across all sites.

Behavioral Theories and Conceptual Frameworks

The use of a strong theoretical design was considered an important aspect of the RFA so that these grants might contribute to a better understanding of how proposed interventions affect health behaviors. All interventions proposed by grantees were theory-based. Appendix D provides a brief primer for each of the theories used by one or more of the nine studies covered in this chapter, as well as the California school-based project (see Chapter 10). The applications of these theories to the intervention designs are discussed in Chapters 9 through 11.

In very brief summary, the model of individual behavior used by several studies was the Transtheoretical, or Stages-of-Change, Model. The models of interpersonal behavior were the Social Cognitive Theory (previously known as the Social Learning Theory) and conceptual frameworks from social networks, social comparisons, and social support. The community and group intervention methods for behavior change were the Diffusion of Innovations and the community organization/organizational change models. Finally, several studies used the PRECEDE-PROCEED planning process to structure the application of their theories.

COLLABORATIVE EFFORTS OF GRANTEES

One of the RFA's specifications was the demonstration of willingness by awardees to collaborate on common analyses where possible. This was accomplished through face-to-face meetings and via conference calls. The result was a set of common questions that all grantees agreed to incorporate into their studies so that some baseline and followup data would be comparable among studies. The common questions consisted of a seven-item food frequency questionnaire (FFQ); stages-of-change questions for children and adults; and questions assessing awareness, knowledge, food preparation (used by some studies), self-efficacy, and demographics (see Appendix E for the common questions).

The seven-item FFQ was developed collaboratively, with input from nutrition assessment experts at NCI. The two questions that summarized total vegetable and fruit consumption were derived from the validated Block FFQ, which used these questions to correct for the overreporting that occurs with a frequency list of vegetables and fruit (Block et al., 1992; Krebs-Smith et al., 1995b). Other questions were added to specify fruit juices, potatoes in various forms, and salads. Asking about french-fried potatoes allowed researchers to remove them from the total count. A similar screener has been validated in adults (Serdula et al., 1993). Several of the nine studies used other nutrition assessment instruments and compared results using several assessments (Baranowski et al., 1997; Hunt et al., 1998).

Two sets of staging questions were developed, one for children and one for adults. Investigators debated whether children would be able to understand the concepts in the questions and whether to focus on eating *more*, as opposed to eating five, servings per day. The choice was to stage on eating more (See Appendix E). A paper on the reliability and validity of stage measures in children was published by researchers in the

Georgia study (Domel et al., 1996). A joint paper on adult stages that included eight of the nine grants indicated that the predominant stages for changing vegetable and fruit consumption were precontemplation, preparation, and maintenance (Campbell et al., 1999).

The awareness and knowledge questions used by all grantees had been previously used in the baseline and followup national surveys to determine whether people had heard of the Program, knew what it meant, and knew how many servings of vegetables and fruit they should eat for the sake of good health. In the national baseline survey, the latter question was a significant predictor of consumption (Krebs-Smith et al., 1995b) (see Appendix E).

The self-efficacy question was included as an important construct from Social Cognitive Theory, which appears to mediate intentions to change. Several grantees also used questions about the amount of responsibility a respondent has for shopping, meal planning, and preparation.

For some grantees, a consequence of incorporating common questions was that they had to omit questions from the surveys that they otherwise might have liked to ask. However, the discussions among grantees about the measurement issues enhanced the quality of all surveys.

One purpose of including common questions on surveys was to enable investigators to produce common papers. A publications policy described the types of publications expected from the grantees: papers with shared analyses, papers with a common theme but individual analyses, and independent papers. The joint papers agreed upon were on baseline consumption outcomes, self-efficacy, and stages of change (Thompson et al., 1999a; Campbell et al., 1999). To produce the common papers, it was necessary to use a data-coordinating center funded by NCI. All sites sent relevant data to the center for the common analyses.

LESSONS LEARNED

There were both benefits to NCI from the entire collaborative research effort as well as lessons learned. Because the concept of the national 5 A Day Program was new and little was known about its potential effectiveness in a variety of community settings, the strategy for the RFA was to obtain a variety of creative approaches that might then be compared. The strategy was successful. The projects had sound research designs, and adherence to the interventions was high. As the following chapters will reveal, the results indicate that the 5 A Day message can effectively change the behaviors of children and adults in a variety of settings, including schools, worksites, and churches, as well as through the WIC program (Buller et al., 1999; Campbell et al., 1999; Havas et al., 1998; Nicklas et al., 1998; Perry et al., 1998; Sorensen et al., 1999).

One value of simultaneously funding a number of projects that are focused on the same or similar outcomes is the ongoing collaboration of researchers over a number of years. Such opportunities to discuss ideas with colleagues who are focused on the same issues add to the quality of the research, which ultimately benefits NCI (or any funding source) and the general public.

The strategy also produced other benefits to nutrition research. These nine grants were the vanguard for a new generation of community-based research. They formed a model for other RFAs and program announcements that were channel-specific and required randomization of large numbers of units.

In addition, the funding of these nine grants sparked interest in the 5 A Day message by other researchers who have subsequently received funding from NIH or other sources for investigator-initiated research. For example, the 5 A Day message was incorporated into a large project grant that involved working with the Cancer Information Service (CIS). A minimal 5 A Day intervention (a brief phone message followed by mailed materials) was successful in several replications in increasing vegetable and fruit consumption levels of CIS callers (Marcus et al., 1998a,b). This project was refunded to assess the impact of tailoring the 5 A Day message on consumption. Results should be available in 2001. Research also is under way with women at high risk of breast cancer to determine if a diet based on 5 A Day recipes, providing 10 to 14 servings of vegetables and fruit a day, will be successful in reducing levels of DNA damage (Thompson et al., 1999b).

These grants revealed that more research continues to be needed on improved methods of dietary assessment. Although the 5 A Day grantees

used a variety of self-assessment methods, there is no clear answer to the question concerning which hierarchy of methods should be applied in community-based research settings.

Perhaps the most important lesson learned from these grants is the need for NCI to develop a process for technology transfer of positive research effects to populations other than the research subjects. This might be done by adding a final optional year to successful projects. For the 5 A Day Program, NCI could convene workshops to be attended by grantees and possible users of the research, such as 5 A Day State coalitions, the Centers for Disease Control and Prevention, the American Cancer Society, the American Heart Association, USDA's Cooperative Extension Service, and industry. The purpose of such a workshop would be to discuss the needs of end users and how research can be translated for their implementation. Researchers would then develop implementation kits and training to facilitate transfer. These products and plans would then be reviewed and revised at a second workshop for the same end users. Finally, the end products would be produced and distributed, enhancing the possibility that more people in the United States would adopt dietary behaviors that might help prevent cancer and other chronic diseases.

SUMMARY

The research initiative that resulted in the funding of the nine 5 A Day grants helped jump-start community-based nutrition research on a national basis, creating a critical mass of interventions with valid scientific designs. The initiative provided NCI with a set of interventions that can be field-tested and implemented throughout the Nation, with the possible long-term outcome of decreasing the incidence rates of a variety of cancers. Results have also indicated where further research is needed.

One of the tasks of NCI's National 5 A Day Program Office is to summarize these results and to perform appropriate transfer of the successful interventions to the State 5 A Day coordinators, other researchers, and voluntary organizations that have national networks for implementing programs. Efforts are under way to transfer results of the North Carolina project through the American Cancer Society and those of the Arizona and Washington State projects through a small business grant. The intention of such technology transfer is to make sure that public funds spent for research ultimately benefit the American public. The dissemination of these results is an important step in reaching national consumption recommendations, which research shows can help reduce the incidence of a variety of cancers.

NCI needs to develop a 5 A Day research strategy for the new millennium. The next steps might include developing RFAs or program announcements that encourage 5 A Day research in new channels, such as restaurants and community organizations (e.g., Boys and Girls Clubs) or new populations (e.g., recent immigrants from Asia and Eastern Europe); combining physical activity and 5 A Day; exploring the effects of public/private partnerships; encouraging a focus on environmental and policy changes that support increased vegetable and fruit consumption; improving social marketing techniques involving new media, such as the Internet; comparing vegetable and fruit consumption and various phytochemicals; and assessing the effects of vegetable and fruit consumption at the cellular level and the effects of vegetable and fruit consumption on cancer survivors.

In summary, the research component of the Program has accomplished what it was designed to do. The next generation of research needs to build toward a variety of tested components in all community channels that ultimately can be implemented communitywide and combined with other lifestyle changes, such as physical activity. To accomplish this implementation, the vision for the future should include an array of set-aside research initiatives, ranging from basic to applied research, such as those initiatives described above. Technology transfer efforts should include field tests to make proven interventions practical for implementation by community organizations and evaluation designs that can be implemented at the local level. In this way, the 5 A Day message can be delivered and adapted as broadly as possible.

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